REMARKS

In the Office Action dated December 28, 2007 claims 1, 3-4, 7-9, 11-12, 14, 28, 35-47 were pending of which claims 1, 4, 7-9, 11-12, 14, 28, and 35-40 were rejected. The Examiner withdrew claims 41-47 from consideration.

By way of this Preliminary Amendment which accompanies the Request for Continued Examination, the Applicants submit that claims 41-47 are now properly included in this Amendment. Accordingly, the claims now pending are 1, 3-4, 7-9, 11-12, 14, 28 and 35-47. Claims 1, 36, and 41 are currently amended. The Applicants submit that support for the present amendments, at a minimum, can be generally found in paragraphs 53, 56, 59, 60, Figure 3, and Figure 4 of the specification.

Claims 36, 37, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,421,349 to Rodriguez et al. ("*Rodriguez*"). Claims 38 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of U.S. Patent No. 6,165,140 to Ferrera ("*Ferrera*"). Claims 1, 4, 7-9, 11-12, 14, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,716,183 to Clayman et al. ("*Clayman*") in view of U.S. Patent No. 5,295,493 to Radisch, Jr. ("*Radisch*") and further in view of U.S. Patent No. 4,925,445 to Sakamoto et al. ("*Sakamoto*"). Claims 28 and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable under *Clayman* in view of *Radisch* further in view of *Sakamoto* and even further in view of *Ferrera*.

Applicants respectfully traverse these rejections. It is noted with appreciation that claim 3 is not now rejected.

I. 35 U.S.C. § 102(b): Claims 36, 37, and 40

Claims 36, 37, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Rodriguez*. The Applicants respectfully traverse this rejection.

A claim is anticipated under § 102(b) only if each and every element set forth in the claim is expressly, or inherently, found in a single prior art reference. *See* MPEP §2131.

Claims 37 and 40 both depend from claim 36, which is in independent form, and now requires, in part, "a guidewire to assist percutaneous endovascular deployment within a thoracic arch region of an aorta comprising . . . a portion of constant reduced diameter . . . having high flexibility and having a tip curve with a radius of curvature of from 5 to 20 mm, the high flexibility and radius of curvature being selected so that the tip curve can bump into the aortic valve without causing damage." The Applicants submit that at least this feature is not taught or disclosed in *Rodriguez*.

Particularly, *Rodriguez* is directed towards a vascular catheter guidewire having a proximal end and a distal end, which are both of higher flexibility than a central portion. (Col. 3, ll. 62-65). The distal end has a tapered down portion and is surrounded by a coil spring. (Col. 2, ll. 66-68). The proximal end has a reduced diameter relative to the main portion and is surrounded by a coil spring. (Col. 3, ll. 25-29). *Rodriguez*, however, does not teach a guidewire having a distal portion having "high flexibility and having a tip curve with a radius of curvature of from 5 to 20 mm, the high flexibility and radius of curvature being selected so that the tip curve can bump into the aortic valve without causing damage."

Rodriguez's discussion of the distal portion of the guidewire is cursory at best, with the focus of *Rodriguez* being directed towards the proximal portion of the guidewire having sufficient flexibility in order to "prevent tearing of rubber gloves, while at the same time still permitting the use of conventional torquing apparatus with the guidewire." (Col. 4, ll. 11-14). *Rodriguez* is completely silent on the claimed features of the distal portion, which requires, among other things, having "a tip curve

with a radius of curvature of from 5 to 20 mm . . . so that the tip curve can bump into the aortic valve without causing damage."

The Applicants submit that the mere reference of the distal portion of the guidewire is insufficient to assert that each and every element set forth in independent claim 36 is expressly, or inherently, found in *Rodriguez*, as required by § 102(b). *See* MPEP §2131. It is for at least these reasons independent claim 36 is patentable over *Rodriguez*. It logically follows that dependent claims 37 and 40 are also in condition for allowance as each of the dependent clams have additional limitations.

II. 35 U.S.C. § 103(a): Claims 1, 4, 7-9, 11-12, 14, 28, 35, 38, and 39

A. Claims 38 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rodriguez* in view of *Ferrera*. The Applicants respectfully traverse this rejection.

Claims 38 and 39 depend from independent claim 36. As discussed in Part I, above, *Rodriguez* fails to teach or disclose each of the limitations found in independent claim 36, which are not now cured by the addition of *Ferrera*. *Ferrera* is directed towards a composite guidewire with a distal tapered portion, a flexible core, and a proximal portion. (Col. 3, ll. 1-7). The guidewire also includes a heat shrinkable material which is disposed over a portion of the guidewire to improve the stiffness of the guidewire. (Col. 2, ll. 59-67); (Col. 3, ll. 42-47).

There is no discussion of the specificities of the distal portion of the guidewire in *Ferrera*, and accordingly, for the same reasons as discussed above, the addition of *Ferrera* does not teach or disclose all of the limitations found in independent claim 36. The allowability of dependent claims 38 and 39 directly follow from the allowability of claim 36.

B. Claims 1, 4, 7-9, 11-12, 14, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Clayman* in view of *Radisch* and further in view of *Sakamoto*. The Applicants respectfully traverse this rejection.

To establish *prima facie* obviousness of a claimed invention, **all** the claim limitations must be taught or suggested by the cited references. *See,* MPEP § 2143.03. In addition, **all** words in a claim must be considered in judging the patentability of the claims over the cited references. *Id.* If an independent claim is nonobvious, then any claim depending from that claim is also nonobvious. *Id.*

Claims 4, 7-9, 11-12, 14, and 28 depend from claim 1. Claim 1, as currently amended, defines a "guide wire to assist percutaneous endovascular deployment within a thoracic arch region of an aorta . . . comprising . . . a tip zone having high flexibility and having a tip curve with a radius of curvature of from 5 to 20 mm, the high flexibility and the radius of curvature being selected so that the tip curve can bump into the aortic valve without causing damage." The radius of curvature allows the tip curve 16 to bump into, but not damage, the aortic valve 21, as shown in Figures 3 and 4, below.

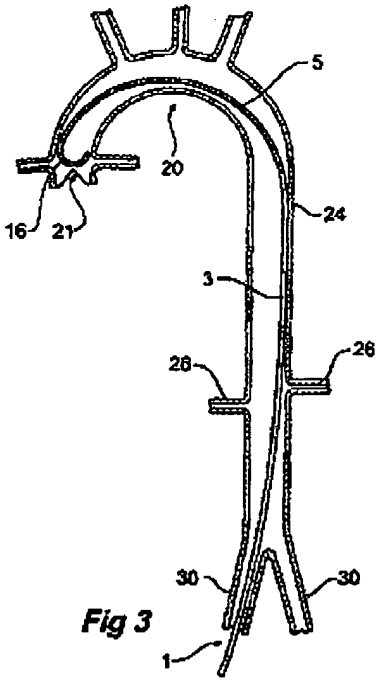

Fig 3

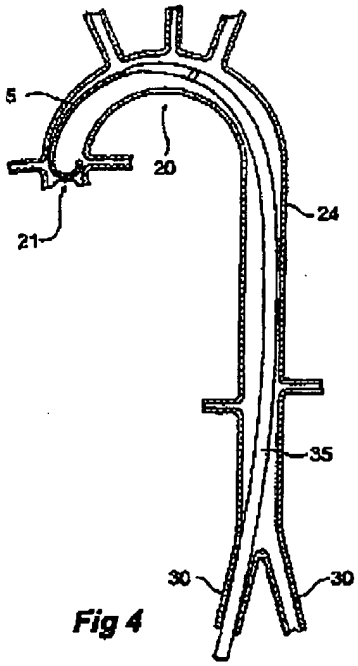

Fig 4

The Applicants submit that the combination of all of these features is not present in *Clayman*, *Radisch*, or *Sakamoto*, individually or in proper combination.

Clayman discloses a urological guide wire having a distal section with a first flexibility, a central section with a second flexibility, and a proximal section with a third flexibility. (Col. 4, ll. 9-15). The intended purpose of *Clayman* is directed towards a guidewire "adapted for insertion and instrument guidance through the urological conduit." (Col. 1, ll. 10-13). Accordingly, *Clayman* does not teach or disclose a guidewire to "assist percutaneous endovascular deployment within a thoracic arch region of an aorta," as required by claim 1. Because *Clayman* is directed towards an entirely different anatomic region of the body, the guide wire disclosed has different physical properties which are customized to the anatomy of

that region. The differences between the anatomic characteristics of the urological conduct and thoracic arch of the aorta correspond to the elements found in independent claim 1, which are not taught or disclosed in *Clayman*.

Specifically, independent claim 1 requires, in part, a "guide wire to assist percutaneous endovascular deployment within a thoracic arch region of an aorta . . . comprising . . . a tip zone having high flexibility and having a tip curve with a radius of curvature of from 5 to 20 mm, the high flexibility and the radius of curvature being selected so that the tip curve can bump into the aortic valve without causing damage." *Clayman* does not contemplate a guide wire having characteristics configured to "bump into the aortic valve without causing damage," and accordingly does not contain all of the elements found in claim 1.

Moreover, these deficiencies are not cured by the addition of *Radisch* or *Sakamoto*. *Radisch* discloses an anatomical guide wire having a predetermined anatomically shaped configuration for introducing an atherectomy cutter into a coronary artery for removing stenosis from the artery. The guide wire is an elongated structure which is made of a suitable strong material that can be formed and maintained in a desired shape. (Col. 4, ll. 15-20). The guide wire is configured to be threaded through the aorta, past the apex 18 (the thoracic arch), and into a coronary artery (such as the RCA), as shown in Figure 1 below. (Col. 4, ll. 26-30).

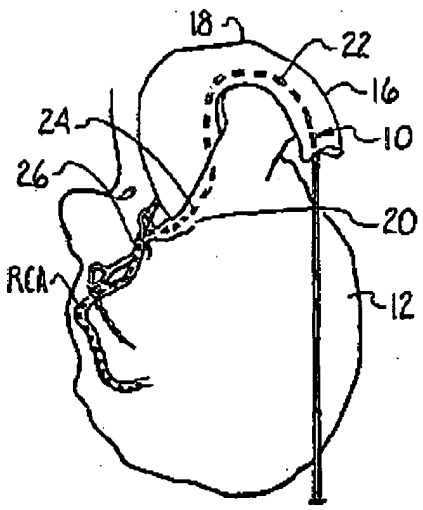

Fig. 1

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The guidewire of *Radisch* is designed to be threaded through the aorta 18 *beyond* the aortic valve. Accordingly, the teachings of Radisch are inapposite to the purpose and claimed features of the present invention, which is a tip zone having "high flexibility" and a "radius of curvature . . . so that the tip curve can bump into the aortic valve without causing damage." The tip curve of the claimed invention has a radius of curvature of from 5 to 20 mm, such that the tip of the tip curve does not damage the aortic valve.

Sakamoto discloses a guide wire for a catheter having a distal end portion comparatively flexible that is formed out of a super-elastic metallic member. *Sakamoto* has a distal tip portion designed to prevent the "distal end portion 12 of the guide wire 10 from piercing the wall of the blood vessel." (Col. 5, ll. 57-60). *Sakamoto* does not contemplate a tip zone with a tip curve that "can bump into the aortic valve without causing damage." The tip curve has "a radius of curvature of

from 5 to 20 mm" such that a portion of the tip curve can bump against the aortic valve without causing damage.

It is for at least these reasons independent claim 1 is patentable over *Clayman*, *Radish*, and *Sakamoto*, alone or in proper combination. It logically follows that dependent claims 4, 7-9, 11-12, 14 and 28 are also in condition for allowance as each of the dependent clams have additional limitations not found in claim 1. In view of these important distinctions, the combination of *Clayman*, *Radish*, and *Sakamoto* would not have made Applicants' invention obvious.

C. Claims 28 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Clayman* in view of *Radisch* further in view of *Sakamoto* and even further in view of *Ferrera*. Claims 28 and 35 depend from claim 1. As discussed above, *Clayman*, *Radisch*, and *Sakamoto*, alone or in combination, do not disclose all of the elements of the claimed invention found in claim 1. Those deficiencies are not cured by the addition of *Ferrera*, for reasons which were discussed in subsection A, above, and will not be reiterated here.

IV. Conclusion

In light of the above, Applicants submit that claims 1, 4, 7-9, 11, 12, 14, 28, and 35-47 are in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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Richard J. Godlewski
Registration No. 30,056
(812) 330-1824
Attorney for Applicants